

## Summary of Safety and Effectiveness

### General Information

Classification: Class II  
Common Name: Image Correlation System  
Device Trade Name: ImageFusion  
Intended Uses: Image processing and comparing an MR and a CT image set or two different CT image sets.  
Predicate Device: RSA StereoPlan  
Establishment Name and Address: Radionics Software Applications, Inc.  
22 Terry Avenue  
Burlington, MA 01803  
Contact Name and Phone: Amy J. LaForte, Ph.D.  
(617) 272-1233  
Establishment Registration Number: 1222895  
Performance Standard: None established under Section 514

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### Substantial Equivalence Determination

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

### Safety Summary

RSA ImageFusion system testing verifies that the registration of MR images in stereotactic CT space is accurate and is approximately  $1.5 \pm 0.6$  mm on average and 2.5 mm maximum for individual landmarks. Further, system and unit testing verify that features such as bone segmentation and landmark alignment, which form the basis of a fusion session, are accurate.

### General Safety and Effectiveness Concerns

The device labeling contains instructions for use. It includes indications for use, cautions, warnings and user quality assurance procedures. The training and installation sessions provide assurance that the user understands all aspects of the ImageFusion System and its intended functionality. This information promotes safe and effective use of the device.

### Description of the Device and Basis for Substantial Equivalence

The ImageFusion system, addressed in this premarket notification, has the same intended use and technological characteristics as the commercially available StereoPlan system. Like StereoPlan, the ImageFusion system includes an image processing work station used to evaluate, manipulate, and compare MR and CT image data. In addition, ImageFusion software can reconstruct (fuse) non-stereotactic MR images into the image space of a reference CT stereotactic image set for subsequent stereotactic use, eliminating the need for the localizing hardware required in StereoPlan to define stereotactic locations in MR images. Subsequently, fused images can be used in the treatment planning for stereotactic neurosurgery, radiosurgery and radiotherapy procedures in the same way that supplementary stereotactic MR or CT images are utilized in StereoPlan.